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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,278	02/22/2001	Michal Linial	P-1476-US	9776

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,278

Applicant(s)

LINIAL ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17, 18 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election of the species drawn to proteins and peptides (claims 1-13, 17, 18, and 21-27 in the Paper filed 2/25/04, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

SEQUENCE RULE NON-COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See, for example, the sequences in Figures 6 and 8. However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks SEQ ID Nos. cited along with each sequence in the Figures. Applicants are also reminded that SEQ ID Nos. are not required in Figures per se, however, the corresponding SEQ ID Nos. then are required in the Brief Description of the Drawings section in the specification. If needed, applicants are required to submit a new computer readable form sequence listing, a paper copy for the specification, and statements under 37 CFR §§ 1.821(f) and (g). Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

ABSTRACT

It is acknowledged that an abstract has been supplied along with the filing under 371. It, however, is not on its own separate sheet of paper. Although the submission of an abstract on its own sheet of paper is not herewith required, it is suggested to do so to prevent processing difficulty, regarding the abstract, that may be associated with the issuance of a patent from this application.

VAGUENESS AND INDEFINITENESS

Claims 1-13, 17, 18, and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, the method is cited as being an "automated method", however, in contrast, none of the specific steps in claim 1 indicate any automation practice. Thus, the claim is vague and indefinite as to whether the phrase "automated method" in line 1 or the specifically cited claim steps without any automation requirement control the metes and bounds of the claim practice. Also, the claim is not clear as to whether automation in line 1 is inclusive of all steps performed in the practice of claim 1 or whether such automation may be directed only to one step and not others. Claim 2 also contains the above unclarities. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claims 1 or 2 also contain this unclarity due to their dependence.

Claim 27 cites the identifying of "families of molecules" in line 1, however, lacks any families limitation as being identified in steps a) or b). In the last 2 lines of claim 27

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the classification of similar function molecules is cited but without stating that such similar molecules are what are meant by the families of line 1. The similar molecules in the last 2 lines of claim 27 may be assumed to be the families of line 1 of the claim, however, such an assumption is not a clear and concise claim practice as required under 35 U.S.C. § 112, second paragraph. Clarification via clearer claim wording is requested.

In claim 1, line 5, the phrase "the position of a selected molecule" is set forth but without clear antecedent basis as to what is meant regarding "position". There is no physical position defined nor a database position defined in the claim. It may be assumed that the position is meant to define a database location, however, such an assumption is not a clear and concise claim practice as required under 35 U.S.C. § 112, second paragraph. This unclarity is also present in instant claim 2, part b), first line therein. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claims 1 or 2 also contain this unclarity due to their dependence.

In claims 24-26 thresholds are cited as numerical values, however, such values are deemed comparative values and lack antecedent basis as to what comparative values are meant corresponding to the specific numerical values in said claims 24-26. Clarification via clearer claim wording is requested as to what is compared to result in evaluating the threshold values of instant claims 24-26.

PRIORITY DOCUMENT CLAIMS

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It is acknowledged that two priority documents have been submitted and claimed regarding priority, which are U.S. Provisional application number 60/072,977 and PCT/IL99/00057. Consideration of these priority documents reveals that priority is not granted to either of said documents. Regarding U.S. Provisional application number 60/072,977 there is no support for the instantly claimed invention regarding a number of limitations in the instant claims. For example, the abstract of 60/072,977 lacks any description of a database which contain groups of clusters or of local consideration as in instant claim 1. Consideration of the remainder of said application 60/072,977 also has failed to reveal support for these limitations. Regarding instant claim 2, a description of first, second, and third sets of expectation values of similarity as related in the claim has not been found in 60/072,977; nor geometric averaging for identifying related clusters with selected molecules as in part iii of instant claim 2. Similarly, the last independent claim 27 cites a storage device containing a first database and a processor connected to said storage device with a second database of sequences which has not been found in 60/072,977. Thus, the disclosure of 60/072,977 fails to support the instant invention limitations and therefore is not granted priority. The other priority document, PCT/IL99/00057 has been submitted in a foreign language and cannot be considered as such. If priority is desired to PCT/IL99/00057, a certified English translation may result in such priority granting.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17, 18, and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jones et al. [Protein Science 7:233-242 (1998)].

Jones et al. summarizes the consensus approach for the assignment of structural domains in proteins in the abstract including several automated methods utilizing software algorithms which is the same type of subject matter as instantly claimed and is directed to instantly elected proteins or peptides (instant claims 17, 18, and 22; proteins are not instantly distinguished from being lengthy peptides as in instant claim 18, or chemicals as in instant claim 22) species embodiments. On pages 234-235 of the reference the consensus approach was applied to 787 proteins as described in the section entitled "Applying the consensus approach to the PDB". This resulted in groupings of related proteins, later defined in clusters in the reference, via single vs. multi-domain groups of proteins. This grouping identification was produced in the reference via domain assignment software algorithms such as DETECTIVE etc. as disclosed in the reference. These software algorithms are summarized in the bridging paragraph between pages 233 and 234 of the reference as assigning domain groupings based on various local considerations. For example, on page 234, first column, lines 6-10, DETECTIVE is disclosed as utilizing the local consideration of an identifiable hydrophobic core, as well as intra-molecular contacts for such assignments as also required in instant claim 1. The above mentioned clustering within the above groups in clusters with related characteristics as instantly claimed is disclosed in the reference in

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the section entitled "Analysis of domain characteristics" on pages 235-239 wherein various clusters of proteins are described. An example of such clusters of related proteins is described as secondary structure protein clusters on page 239, first column, first paragraph. The classification of similar biologic function of selected molecules as required in part b) of instant claim 1 is set forth in the reference in that selected molecules are classified which are similar as being enzymes. This is demonstrated in Figures 4 and 5, for example, on pages 236 and 237 wherein several enzymes are classified via domain characteristics etc. Thus, the reference anticipates instant claims 1 and 17.

Claims 1, 17, 18, 21, and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by either of Levitt et al. [Nature 261:552-558 (1976)] or Orengo et al. [Protein Engineering 6(5) : 485-500 (1993)].

Equivalent to the above Jones et al. reference, Levitt et al. and Orengo et al. classify proteins into families or groups with similar biologic function with clustering therein via local consideration of fold structures. Levitt et al. discloses such in the title and abstract in summary and in the document as a whole and specifically depicts this on page 556 in Table 1. It is noted that immunoglobulins are included as required in instant claim 21. Also equivalently Orengo et al. identifies and classifies protein fold families as summarized in the title and abstract. Hierarchical organization is shown as a result on pages 488-491 in Table I, also inclusive of the instantly claimed immunoglobulins as set forth on page 488, near the bottom in the section entitled "BETA: GREEK KEY".

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. [Protein Science 7:233-242 (1998)].

Jones et al. utilizes a method of domain clustering and grouping as described in the above rejection which is thus stored as results from the assignment programs as evidenced that these results (first database) are available for analysis as described above. These disclosures thus describe part a) of instant claim 27. The processor part b) of instant claim 27 is described in the reference in that it is connected to a Protein Database (PDB) (second database as instantly claimed) to operate software algorithms such as DETECTIVE thereon to produce the classification of similar biologic enzyme function automatically via said software.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention that the above descriptions of assignment programs with result analysis from an enzyme database would be required to be automatically

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performed on a processor with a storage device as in instant claim 27 given the above summarized descriptions in Jones et al.

INFORMALITIES

The disclosure is objected to because of the following informalities.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See the specification on page 46, line 21.

Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The print size is too small regarding the citations listed in the specification on pages 46-49. Lettering style having capital letters which are at least 0.21 cm (0.08 inch) high is required. See the MPEP at 608.01 under PAPER REQUIREMENTS.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

May 28, 2004

Ardin H. Marschel 5/28/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER